

21 CFR part or guidance	Topic	OMB control No.
807, subpart E .....	Premarket notification .....	0910-0120
814, subparts A through E .....	Premarket approval .....	0910-0231
812 .....	Investigational Device Exemption .....	0910-0078
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff".	Q-submissions .....	0910-0756
50, 56 .....	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910-0755
56 .....	Institutional Review Boards .....	0910-0130

Dated: May 14, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-10599 Filed 5-19-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0033]

#### **Morton Grove Pharmaceuticals Inc. et al.; Withdrawal of Approval of Seven Abbreviated New Drug Applications; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of March 5, 2021. The document announced the withdrawal of approval of seven abbreviated new drug applications (ANDAs) from multiple applicants as of April 5, 2021. The document indicated that FDA was withdrawing approval of the following five ANDAs, after receiving a withdrawal request from Neopharma, Inc., 211 College Road East, Suite 101, Princeton, NJ 08540: ANDA 078383, Pioglitazone Hydrochloride (HCl) Tablets, Equivalent to (EQ) 15 milligrams (mg) base, EQ 30 mg base, and EQ 45 mg base; ANDA 078953, Irinotecan HCl Injection, 40 mg/2 milliliters (mL) (20 mg/mL) and 100 mg/5 mL (20 mg/mL); ANDA 079049, Alendronate Sodium Tablets, EQ 5 mg base, EQ 10 mg base, EQ 35 mg base, and EQ 70 mg base; ANDA 090732, Anastrozole Tablets, 1 mg; and ANDA 203161, Irbesartan Tablets, 75 mg, 150 mg, and 300 mg. Before FDA withdrew the approval of these ANDAs, Neopharma, Inc., informed FDA that it did not want the approval of the ANDAs withdrawn. Because Neopharma, Inc., timely requested that approval of these ANDAs not be withdrawn, the approval

of ANDAs 078383, 078953, 079049, 090732, and 203161 is still in effect.

#### **FOR FURTHER INFORMATION CONTACT:**

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Friday, March 5, 2021 (86 FR 12950), appearing on page 12950 in FR Doc. 2021-04520, the following corrections are made on pages 12950 and 12951 in the table:

The entries for ANDAs 078383, 078953, 079049, 090732, and 203161 are removed.

Dated: May 14, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-10588 Filed 5-19-21; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-P-0162]

#### **Determination That NORMODYNE (Labetalol Hydrochloride) Injection, 5 Milligrams per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that NORMODYNE (labetalol hydrochloride) injection, 5 milligrams per milliliter (mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the

product as long as they meet relevant legal and regulatory requirements.

#### **FOR FURTHER INFORMATION CONTACT:**

Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3600, [Christopher.Koepke@fda.hhs.gov](mailto:Christopher.Koepke@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).

FDA may not approve an ANDA that does not refer to a listed drug.

NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, is the subject of NDA 018686, held by Schering Corp., and initially approved on August 1, 1984. NORMODYNE is indicated for control of blood pressure in severe hypertension.

In a letter dated September 28, 2004, Schering Corp. notified FDA that NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, was being discontinued and requested withdrawal of NDA 018686 for NORMODYNE (labetalol hydrochloride), and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In the **Federal Register** of June 16, 2006 (71 FR 34940), FDA announced that it was withdrawing approval of NDA 018686, effective June 16, 2006.

Nexsen Pruet, LLC, submitted a citizen petition dated February 4, 2021 (Docket No. FDA-2021-P-0162), under 21 CFR 10.30, requesting that the Agency determine whether NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved

by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 14, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-10594 Filed 5-19-21; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-2494]

#### Peripheral Vascular Atherectomy Devices—Premarket Notification Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Peripheral Vascular Atherectomy Devices—Premarket Notification Submissions." This guidance provides updated recommendations for premarket submissions for a new or modified peripheral vascular atherectomy device.

**DATES:** The announcement of the guidance is published in the **Federal Register** on May 20, 2021.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include Docket No. FDA-2018-D-2494 for "Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked